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09/870,009	05/30/2001	Hisashi Kashima	JP920000069US1	8419

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EXAMINER

SMITH, CAROLYN L

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 01/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/870,009

Applicant(s)

KASHIMA ET AL.

Examiner

Carolyn L. Smith

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10/31/05.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 5,8-12,15,17-27 and 30-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 5,8-12,15,17-27 and 30-34 is/are rejected.
- 7) ☒ Claim(s) 23 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Applicant's remarks in the Appeal Brief, filed 10/31/05, are acknowledged.

In view of the Appeal Brief filed on 10/31/05, PROSECUTION IS HEREBY REOPENED. The following rejections are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below.

Rejections and/or objections not reiterated from the previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 5, 8-12, 15, 17-27, and 30-34 are herein under examination.

***Claim Objection***

Claim 23 is objected to because of the following informality: Claim 23, line 2, recites the phrase “and is” which is grammatically awkward. Appropriate correction is required.

***Claim Rejections - 35 USC § 112, first paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 32 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 32 recites a “portion which is other than said gene portion comprises a portion of said DNA which does not store a protein code sequence and transcription control information for said sequence” which does not appear to have adequate support in the specification, claims, and drawings, as originally filed. On page 13, lines 3-6, of the specification, states “a gene portion wherein a protein code sequence and its transcription control information are stored, and a portion wherein genetic information is not included”. This statement does not provide written support for the “portion which is other than said gene portion” mentioned in new claim 32 because this portion on page 13 merely states that genetic information is not included. “Genetic information” and “protein code sequence and its transcription code information” differ in scope. It is also noted that one of skill in the art would recognize “genetic information” to include

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nucleotides which may be present in the “portion which is other than said gene portion” such that genetic information is actually included. Because the introduction of the phrase “portion which is other than said gene portion comprises a portion of said DNA which does not store a protein code sequence and transcription control information for said sequence” does not appear to have adequate support in the specification, claims, and drawings, as originally filed, this phrase is considered to be NEW MATTER.

In the Appeal Brief, filed 10/31/05, Appellants argued that claim 32 was rejected as allegedly not enabled. This statement is found confusing as the 35 USC 112, 1<sup>st</sup> paragraph rejection was a NEW MATTER rejection, not a lack of enablement rejection. Appellants argued that MPEP 2163 states a patent specification need only describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. While this statement is true, it was noted in the NEW MATTER rejection that “genetic information” (as mentioned by Appellants on pages 12-13 of the application) and “protein code sequence and its transcription code information” (amended claim limitation) differ in scope. Therefore, there does not appear to be written support for the rejected phrase “a portion which is other than said gene portion comprises a portion of said DNA which does not store a protein code sequence and transcription control information for said sequence”. Appellants argued that it was completely unreasonable to suggest that the specification does not describe the claimed invention of instant claim 32 in sufficient detail. This statement is found unpersuasive as the Appellants failed to point to adequate written support in the originally filed application. Appellants’ arguments regarding alleged written support on

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pages 12-13 are unpersuasive for the reasons already addressed above. Appellants argue that there was a failure to establish that claim 32 was not enabled under 35 USC 112, 1<sup>st</sup> paragraph. It is reiterated that the 35 USC 112, 1<sup>st</sup> paragraph, was a NEW MATTER rejection and not a lack of enablement rejection.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 recites the phrase “intentionally designed” which is vague and indefinite. It is unclear what limitation of a nucleic acid or structure is intended by the recitation that it be “intentionally designed”. In addition, it is unclear what is considered to be an “unintentionally designed” nucleic acid. Clarification of this issue via clearer claim wording is requested. Claims 9-10 are also rejected due to their dependency from claim 8.

### **PRIOR ART**

Applicant's arguments with respect to claims 5, 8-12, 15, 17-27, and 30-34 have been considered but are moot regarding the prior art in view of the new ground(s) of rejection.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 5, 8-12, 15, 17-27, and 30-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Lizardi (US 5,854,033).

Lizardi discloses detecting mutations in target sequence genes, for example the identified gene responsible for Huntington's chorea by designing an open circle probe (col. 22, lines 20-37), Figure 1 shows a open circle probe hybridized to a target sequence, and Figure 5 shows an open circle probe with detection tags which represents a first gene portion including a predetermined gene for Huntington's chorea, a second portion which is other than said gene portion (=probe), and a not naturally occurring nucleotide sequence (=detection tag) which is embedded in portion other than said gene portion with source identification information of said predetermined gene, as stated in instant claims 5, 8, 11, 12, 15, and 27. Lizardi discloses DNA ligation which circularizes a specially designed nucleic acid probe used to detect the presence of specific nucleic acids in a sample (abstract) containing the detection tags (Figure 5) which represents a special sequence that is intentionally designed and included as part of the nucleotide sequence, as stated in instant claim 8. Figure 5 shows multiple detection tags, a primer complement, a promoter, and target probes which represent at least one special sequence with a plurality of sequences having a plurality of types of patterns (=different sequence patterns)

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embedded at predetermined locations of DNA, as stated in instant claims 9, 10, and 18-20.

Lizardi discloses in situ hybridization in cytogenetics (col. 23, lines 1-10) which encompasses a cell of an organism, as stated in instant claim 12. Lizardi discloses detecting various mutant genes (Examples 2 and 3) which represent a value-added gene that is provided by gene manipulation, as stated in instant claim 17. Lizardi discloses copies of the open circle probe in Figure 11b which represents copy tolerance, as stated in instant claim 21. Lizardi discloses the detection tag portions of the open circle probe may have 60 tag portions or less with same or different sequences which can be any length that supports specific and stable hybridization between tags and the probes (col. 7, lines 6-31) which represents embedding at random locations as well as watermark (=specific sequences), as stated in instant claims 22 and 30. The detection portion of the open circle probe is separate from the target sequence containing the gene (Figure 5 and 8) which represents the at least one nucleotide sequence is not naturally generated through gene mutation, as stated in instant claim 23. Lizardi discloses using enzyme-linked detection systems (abstract) and Figure 5 shows the promoter of the open circle probe, as stated in instant claim 24. Lizardi discloses if any target sequences are present then the open circle probe ligates to it and detection tags allow for detection (col. 22, lines 37-49) which represents detecting a complementary sequence, as stated in instant claim 25. Figure 5 gives an example of detection tags being embedded at predetermined locations, as stated in instant claim 26. The genes in Examples 2 and 3 represent protein code sequence and Figure 8 shows transcriptional initiation sites, as stated in instant claim 31. Figure 5 shows detection tag portions which represent a portion which is other than said gene portion that does not store protein code sequence and transcriptional control information, as stated in instant claim 32. Figure 10 shows amplified



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RNA which represents gene portion transcribed into RNA and portion other than said gene portion is not transcribed, as stated in instant claim 34. Lizardi discloses using oligonucleotides for wild type and mutant gene detection via ligation (col. 36, line 19 to col. 37, line 20 and col. 38, line 48 to col. 39, line 67) which represents producing a gene by artificial, intentional manipulation, as stated in instant claim 33. Lizardi discloses including a unique address tag within the spacer region of the open circle probe so that tandem sequence DNA generated from a given open circle probe will contain sequences corresponding to a specific address tag sequence (col. 22, lines 13-18).

Thus, Lizardi anticipates the instant invention.

Claims 5, 8-11, 15, 17-27, 30, and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Arnot et al. (Molecular and Biochemical Parasitology, Volume 61, 1993) with additional support from Merriam-Webster online dictionary ("embed" definition).

Arnot et al. disclose genomic DNA including CS gene of *Plasmodium falciparum* (abstract and page 17, col. 1, last paragraph) which represents DNA including a predetermined gene, as stated in instant claim 5 and (=first portion) in instant claim 15. Figure 2 shows the CS gene with CS repeats (=gene portion) along with the 5' flanking region wherein the flanking region represents a portion which is other than the gene portion, as stated in instant claim 5 and (=second portion) in instant claim 15. Figure 1 shows two types of tandem repeat primers with TAG sequences bound to the genomic sequence. It is noted that Merriam-Webster online

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dictionary defines “embed” as to make something an integral part of. Arnot et al. disclose hybridizing probes in a strategy to extract information on sequence variation called DNA barcodes to identify parasite stocks and lineages (abstract) while Figure 2 shows using a CS region flanking primer as well as a TAGed Type I complement primer wherein the primers represent not naturally occurring nucleotide sequences and the flanking primer represents a sequence embedded in portion other than said gene portion which identifies source of predetermined gene, as stated in instant claims 5, 8, 11, 15, and 27. Arnot et al. disclose designing specific primers (page 16, col. 1, second paragraph; page 16, col. 2, last paragraph to page 17, col. 1, first paragraph) wherein the primers represent intentionally designed special sequence, as stated in instant claim 8. Arnot et al. disclose amplifying DNA fragments using the flanking and TAG complement primer (page 18, col. 1, first paragraph). Table 1 (and its caption) lists interspersions of variant tandem repeats hybridized to primers and transformed into barcodes for CS genes of 20 isolates of *P. falciparum* which represents a plurality of sequences embedded at predetermined locations (as stated in instant claims 9 and 19) and Figures 2 and 3 show a plurality of sequences having a plurality of types of patterns embedded at predetermined locations of DNA, as stated in instant claims 10 and 18. The different primers and sequence lengths (i.e. page 16, last paragraph to page 17, first paragraph; Figure 2c) represent different nucleotide sequences, as stated in instant claim 20. Arnot et al. disclose DNA probes that hybridize to many dispersed mini-satellite loci simultaneously to produce an individual specific genome fingerprint (page 15, col. 1, first paragraph). Arnot et al. disclose the ability to trace malarial infection with the CS locus barcode to identify routes of infection and persistent foci and unusually infectious individuals (page 23, col. 1, last paragraph)

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which represents a value-added gene provided by selective breeding wherein the ability to trace infection routes represent value of the gene, as stated in instant claim 17. Arnot et al. disclose the unique “barcodes” among various isolates of *P. falciparum* in Table 1 and identifying lineages from these barcodes (abstract) which represents at least one nucleotide sequence is copy tolerant, as stated in instant claim 21. Figure 2c-d shows a TAGed Type I complement primer randomly attached to one of the Type I CS repeats which is amplified also using the flanking primer which represents a sequence embedded at a random location, as stated in instant claim 22. Arnot et al. disclose designing specific primers (page 16, col. 1, second paragraph) which represents a sequence not naturally generated through gene mutation, as stated in instant claim 23. Arnot et al. disclose producing radiolabelled marker fragments by 3' end labeling a MspI digest of pBR322 using [32P]dCTP and the Klenow enzyme (page 17, col. 1, second paragraph) which represents one of a restrictive enzyme identification sequence and a promoter, as stated in instant claim 24. Arnot et al. disclose using a TAG sequence on the 5' end of primers that are complementary to the tandem repeats of the genomic sequence (Figure 1) as well as results using 32P-labelled PCR products (Figure 3) which represents at least one nucleotide sequence is detectable using a nucleotide sequence that is complementary to said at least one nucleotide sequence, as stated in instant claim 25. Figure 2 shows that Type I CS repeats occur in certain predetermined locations, including the flanking primer embedded in its specific location, as stated in instant claim 26. Table 1 shows patterns of variant tandem repeats with barcoding results which represents a watermark sequence, as stated in instant claim 30. Arnot et al. disclose the CS gene region and flanking region (Figure 2) as well as genomic sequences with unexpressed tandemly repeated DNA sequences (abstract) which represents gene portion

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transcribed into RNA and other said portion not transcribed into RNA, as stated in instant claim

34.

Thus, Arnot et al. anticipate the limitations in instant claims 5, 8-11, 15, 17-27, 30, and

34.

### ***Conclusion***

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The Central Fax Center number for official correspondence is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (571) 272-0721. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached on (571) 272-0718.

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Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner Tina Plunkett whose telephone number is (571) 272-0549.

January 17, 2006

**MARJORIE A. MORAN**  
**PRIMARY EXAMINER**

*Marjorie A. Moran*  
*1/19/06*

*Ardin H. Marschel* *1/19/06*  
**ARDIN H. MARSCHEL**  
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